

REMARKS

Claims 1-18 are pending after entry of this paper. Claims 1-18 have been subjected to election of an invention group for prosecution on the merits under 35 U.S.C. §§121 & 372. Claims 9-18 have been amended to correct the multiple dependency, i.e., multiple dependent claims depending from multiple dependant claims. Claims 5-8 and 17 have been provisionally withdrawn. No new matter has been introduced by these amendments.

Response to Restriction Requirement under 35 U.S.C. §§121 & 372

Claims 1-18 have been subjected to election of an invention group for prosecution on the merits under 35 U.S.C. §§121 & 372. In the Examiner's opinion, as set forth in the Detailed Action, the application contains inventions or groups of inventions, which are not linked to form a single general inventive concept under PCT Rule 13.1. The Office Action alleges that the application contains claims directed to three (3) patentably distinct species as follows:

Species I: *Listeria monocytogenes*.

Species II: *E.coli*.

Species III: *Salmonella*.

Depending on the species elected, the Examiner also requested an election of primers from SEQ ID NOs: 1 to 10. Specifically, the Examiner requests an election of one set of primers presented in SEQ ID NOs: 1 to 6 or one set of primers presented in SEQ ID NOs: 5 to 10.

Applicants respectfully request that the Restriction Requirement be withdrawn and all claims be examined together on the merits. Nonetheless, in response to the Restriction

Requirement, applicants **provisionally elect *Listeria* species and primers presented in SEQ ID NOs: 5 to 6 with traverse**, including **claims 1-4, 9-16, and 18**.

However, applicants respectfully disagree with the restriction requirement imposed by the Examiner since such restriction requirement impedes the main feature of the present invention, *i.e.*, multiple microorganisms detection in a single operation. The invention is directed to a method of multiple microorganism detection (*i.e.*, two or more microorganisms having different properties in food) with a single multiplex PCR. In other words, the method provides a novel approach to detecting contaminating microorganisms including, for example, pathogenic *Escherichia coli*, *Listeria monocytogenes* and *Salmonella* species by using a single multiplex PCR reaction and plural pairs of primers. Therefore, an election of single species goes against the essential nature of the instant invention, which is to detect multiple species and **not a single species**. In fact, the method for detecting one type of microorganism by PCR (*i.e.*, single species) have already been established and is known in the art. Therefore, applicants assert that such election of species alters the essential nature and novelty of the present invention and should be reconsidered by the Examiner.

Furthermore, applicants respectfully submit that primers presented as SEQ ID NOs: 1 to 10 should be examined for the merits together. According to MPEP 803.04,

[t]o further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Director has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. . . .

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. (emphasis added)

Thus, applicants respectfully assert that in accordance with MPEP 803.04, the required election of primers selected from ten very short nucleotide sequences (SEQ ID NOs: 1 to 10) should be reconsidered and waived from the requirements of 37 CFR 1.141 in recognition of the “Director’s” desire to promote and aid the biotechnology industry. At the very least, the primers in SEQ ID NOs: 1 to 6 should be examined together for the merits because as discussed *supra* the present invention is directed to multiple microorganisms detection in a single operation. In order to detect the presence of pathogenic *Escherichia coli*, *Listeria monocytogenes* and *Salmonella* in a single operation, the claimed method would require at least primers disclosed in SEQ ID NOs: 1 to 6.

Therefore, applicants respectfully traverse the requirement for election on the grounds that (1) such election of species interferes with the essential feature of the disclosed invention and (2) examining ten primers presented in SEQ ID NOs.: 1-10 is not burdensome and permitted by the Patent Office under the directive presented in MPEP 803.04. Therefore, reconsideration and withdrawal of the restriction/election is respectfully requested.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the restriction requirement imposed on the pending claims and allowance of this application. Favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-4827**, Order No. 1004451.001US.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-4827**, Order No. 1004451.001US.

Respectfully submitted,
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By:



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